Department of Veterans' Affairs
Harry S. Truman Memorial Veterans' Hospital
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Columbia, MO 65201

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Issued by: Research

Research Informed Consent

1. **PURPOSE**: To describe the policies and procedures for obtaining informed consent from research participants.

2. **POLICY**: The Veterans' Administration (VA) is one of the 16 departments and agencies that have agreed to follow the Federal Policy for the Protection of Human Subjects, effective August 19, 1991. This policy is incorporated in 38 CFR 16. The Veterans' Health Administration (VHA) national regulations concerning the use of human subjects in research are found in VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research." The provisions of this policy apply to all research involving human subjects conducted completely or partially in VA facilities including research funded from extra-VA sources and research conducted without direct funding. The Handbook outlines the purpose, authorities, and responsibilities of VHA staff in the conduct of human research. The policy of this facility is that all requirements and responsibilities described in VHA Handbook 1200.5 will be strictly followed.

3. **RESPONSIBILITY**: Investigators who are involved in human subject research will obtain informed consent from the subject or the subject's legally authorized representative.

4. **PROCEDURE**: Informed consent will be documented by the use of a written consent form (VA Form 10-1086) and signed by the subject or the subject's legally authorized representative, except as indicated in the Handbook. Additional procedures associated with research informed consent are as follows:

a. Human research protocols, including the informed consent documentation, must be approved by both the Institutional Review Board (IRB) and the Research and Development (R&D) Committee.

b. Research informed consent documentation must be developed in accordance with VHA Handbook 1200.5 "Requirements for the Protection of Human Subjects in Research."

c. The consent documentation must bear the stamp of the IRB dated at the time of approval; the most recently approved consent documentation will be used.

d. The research consent form must be written in lay language at approximately the sixth grade level.

e. Research team members who obtain informed consent from participants will be credentialed through the Research Office and will demonstrate evidence of all mandated training.

f. A Health Insurance Portability and Accountability Act (HIPAA) authorization must be obtained from each human participant.

g. Informed consent must be obtained from human participants under conditions that eliminate or properly manage conflicts of interest.

h. The prerogative of persons to decline participation in research studies will be respected.

i. Participants will be given a copy of the consent documentation. Original copies of the documentation will be retained by the investigator; photocopies will be forwarded to the IRB.

j. A copy of the research informed consent will be scanned into the participant's electronic medical record.

k. In emergency situations in which a study drug or procedure is expected to benefit the subject and no equal alternatives are available, consent may be given by the Chief of Staff if the patient has been adjudged to be incompetent, or is unable to provide authorization, unable to comprehend significance of consent actions, unable to exercise judgment, is unconscious, or is otherwise unable to give consent.

4. **REFERENCES**: VHA Handbook 1200.5, dated July 15, 2003

5. **FOLLOW-UP RESPONSIBILITY**: Research Compliance Officer, Research Service

6. **RECISSION**: None

APPROVED:

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